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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,126

06/21/2006

Jacques Thilly

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EXAMINER

MAUST, TIMOTHY LEWIS

ART UNIT

PAPER NUMBER

3751

MAIL DATE

DELIVERY MODE

11/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/554,126	Applicant(s) THILLY ET AL.	
	Examiner Timothy L. Maust	Art Unit 3751	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/21/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 1 is objected to because of the following informalities: Line 14; the phrase “and closure. flow” is grammatically incorrect. Appropriate correction is required.

Drawings

The drawings filed on 10/21/05 are informal, since the letters, numbers and lines are not uniform in nature throughout the Figures.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 1-6 and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Choksi et al. (4058121).

Regarding claims 1, 5, 6 the Choksi et al. reference discloses an apparatus (Figure 1) for introducing a liquid into a pharmaceutical container having a puncturable closure, comprising;

a hollow needle (1) suitable for passing through the closure, the needle comprising a tubular conduit (4) defined by a side wall and having an internal bore (12) for the flow of a fluid along the bore in an flow direction, the conduit terminating externally at a pointed end (19), the bore terminating internally at a closed end (18), at

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least one orifice (25, 26) through the side wall for the exit of fluid flowing along the bore, the at least one orifice being oriented to direct liquid flowing along the bore in a direction having a component parallel to the flow direction, the conduit having at least one vent groove (27) in its outer surface; means to cause the needle to puncture the closure to the extent that the at least one orifice is within the container (defined by applying pressure to syringe 2 by a user); means to cause the liquid to flow along the bore (defined by plunger 8); means to withdraw the needle from the container (defined by withdrawing syringe 2 by a user).

Regarding claim 2, further comprising means to hold the needle and support the container (defined by wings 20 and 21; the container is support by a hand of a user or a table), and to cause them to move relatively together along the longitudinal axis of the needle.

Regarding claim 3, wherein the container is a vial (defined by vial 5) supported with its closure uppermost, and the needle is held above the container and moved downwardly toward the closure.

Regarding claim 4, inasmuch structure that is defined by a conveyor, a user's arm would meet the claim limitation by conveying the vials from one location to another.

Regarding claims 12-16, the process as claimed would be inherent during use and operation of the device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choksi et al.

Regarding claim 7, the Choksi et al. reference discloses the invention substantially as claimed (discussed supra), but doesn't disclose the pointed end of the conduit being a separate plug part. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the pointed end of the Choksi needle a separate plug part, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 150 U.S. 168; USPQ 177, 179.

Regarding claim 8, Choksi shows in Figure 3 an internal closed end (18) having surfaces that converge toward an upstream direction (defined by end 13), but doesn't disclose the orifice perimeter surfaces being between 10 and 60 degrees relative to the upstream direction and the total cross sectional area being +/- 20% of the cross sectional bore of the conduit. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ orifice perimeter surfaces between 10 and 60 degrees and have a total cross sectional area being +/- 20%, since it has

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been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617F 2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claims 9-11, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process (see MPEP 2113).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited prior art pertains to various needle devices having similar structure to that of the Applicant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy L. Maust whose telephone number is (571) 272-4891. The examiner can normally be reached on Mon. - Thur. 7:00-5:30pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy L Maust/
Primary Examiner
Art Unit 3751

11/24/08